EXHIBIT 14
DATE 2/17/09
HB 482

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

APHIS 91–45–011

Brucellosis Eradication:

Uniform Methods and Rules, Effective February 1, 1998

Excerpt from full document

The plan should also include other appropriate practices to confine and eliminate the disease.

3. When suspects are found in any herds, a similar individual herd plan may be initiated. This plan should include testing schedules and management plans that will minimize spread of brucellosis within the herd or to other herds.

4. For heifers and heifer calves in herds known to be affected, the plan must contain the following restrictions:

   a. All heifer herds must be included under the quarantine.

   b. All heifer calves between 4 and 8 months of age at the time the herd is quarantined must be officially vaccinated for brucellosis or identified with an official eartag.

   c. All non-*Brucella abortus* Strain 19-vaccinated heifer calves over 8 months of age must be considered test eligible and must be included in all herd tests if kept in the herd.

   d. All *Brucella abortus* Strain 19 calfhood-vaccinated heifers remaining in the herd must be included in all herd tests, provided that the animals have been vaccinated for at least 6 months.

   e. All vaccinated heifer calves that have been vaccinated for at least 6 months and all nonvaccinated heifer calves at least 8 months of age that are maintained separately from the adult herd immediately after weaning must be included on the 6-month postquarantine release test. It is recommended that all heifers be tested immediately prior to breeding and at appropriate intervals thereafter until they have calved.

F. Herd Depopulation

Among the strategies for eradicating the disease, State and Federal animal health personnel should consider depopulating brucellosis-affected herds that have a high rate of infection or an infection of long duration, or affected herds found in areas that were previously free of brucellosis.

G. Retesting Reactors

Within 3 days after being notified of the results of an initial herd blood test, the owner may request an additional blood test on reactors at his or her own expense. The request must be based on sound epidemiologic evidence, and all animals must remain under herd quarantine.

H. Reclassifying Reactors

Under certain conditions, reactors may be eligible for reclassification, as provided for in chapter 1, part II, section 7G.

I. Recognition of Certified Brucellosis-Free Herds

The State animal health official and the APHIS AVIC will issue a Brucellosis-Free Herd certificate when the herd first qualifies for this status.

When the herd qualifies for recertification, the State animal health official will issue a certification renewal form showing the herd certification number, the number of animals, and the owner.

Part II. Class Free Status

A State or area that achieves Class Free status is officially recognized as being free of brucellosis in cattle and bison. This part of the UM&R covers the requirements for establishing and maintaining Class Free status in a State or an area. It also covers the requirements for moving cattle and bison from and within Class Free States and areas.

1. Size of Area

Class Free status usually applies to an entire State. However, a State may request a two-area classification.

A State must meet all of the following specific criteria to receive approval of a two-area classification:

A. Legislative authority—

Legislative authority must exist for maintaining separate areas within the State.

B. Regulatory authority—

Regulatory authority must exist for maintaining separate areas within the State.

C. Resources—

Resources must exist and must be committed to maintaining separate areas within the State.

D. Method—

A creditable method must exist for monitoring and controlling the movement of animals across the area boundary, and its effectiveness must be demonstrated. APHIS will review the procedures with the requesting State.

2. Duration of Status

A State or area will retain its Class Free status indefinitely, provided that it continues to meet the requirements for Class Free status. If a single affected herd is found in a Class Free State, the State may retain its Class Free status if it meets the following conditions, which must be satisfied within 60 days of the identification of the affected animal: (1) The affected herd must be immediately quarantined, tested for brucello-

sis, and depopulated; and (2) an epidemiologic investigation must be performed, and the investigation must confirm that brucellosis has not spread from the affected herd. All adjacent herds, source herds, and contact herds must be epidemiologically investigated, and each of those herds must receive a complete herd test with negative results.

A review will be conducted to determine that all of the provisions as outlined above have been satisfied. If the above conditions are not met, Class Free status is automatically suspended if field-strain *Brucella abortus* infection is found, except when the field-strain infection is found to be imported and brucellosis has not spread to other herds before the exposed animals have been returned to the State of origin or slaughtered.

Every 12 months, all States must prepare an annual report summarizing their brucellosis program activities for the previous 12 months. The annual report must include the following information:

A. Herd and cattle/bison population and the source of this information;

B. The dates of the reporting period;

C. The number of BMST rounds completed during the reporting period;

D. The number of MCI tests (slaughter MCI and all other MCI tests are to be reported separately);

E. The number of MCI reactors;

F. The number of MCI reactors traced by category, such as those traced to:

   1. A herd of origin in which reactors were found on the herd blood test,

   2. A herd of origin that had negative results on the herd blood test,

   3. Out-of-State origins, or

   4. Known infected herds.

G. The number of cows and bulls 2 years of age and older that were slaughtered and the number of blood samples that were collected from these animals;

H. The number of herds infected with field strains of *Brucella abortus* during the reporting period;

I. The number and results of blood tests of other species of domes tic animals;

(Items A through I are to be reported on revised VS Form 4–1, Application for Status. Almost all of the information required is available on VS or Brucellosis Recording and Reporting Systems [BRRS] Forms 4–33D and 4–54D [Monthly Reports on Brucellosis Eradication Activities], which are kept on file in each State.)

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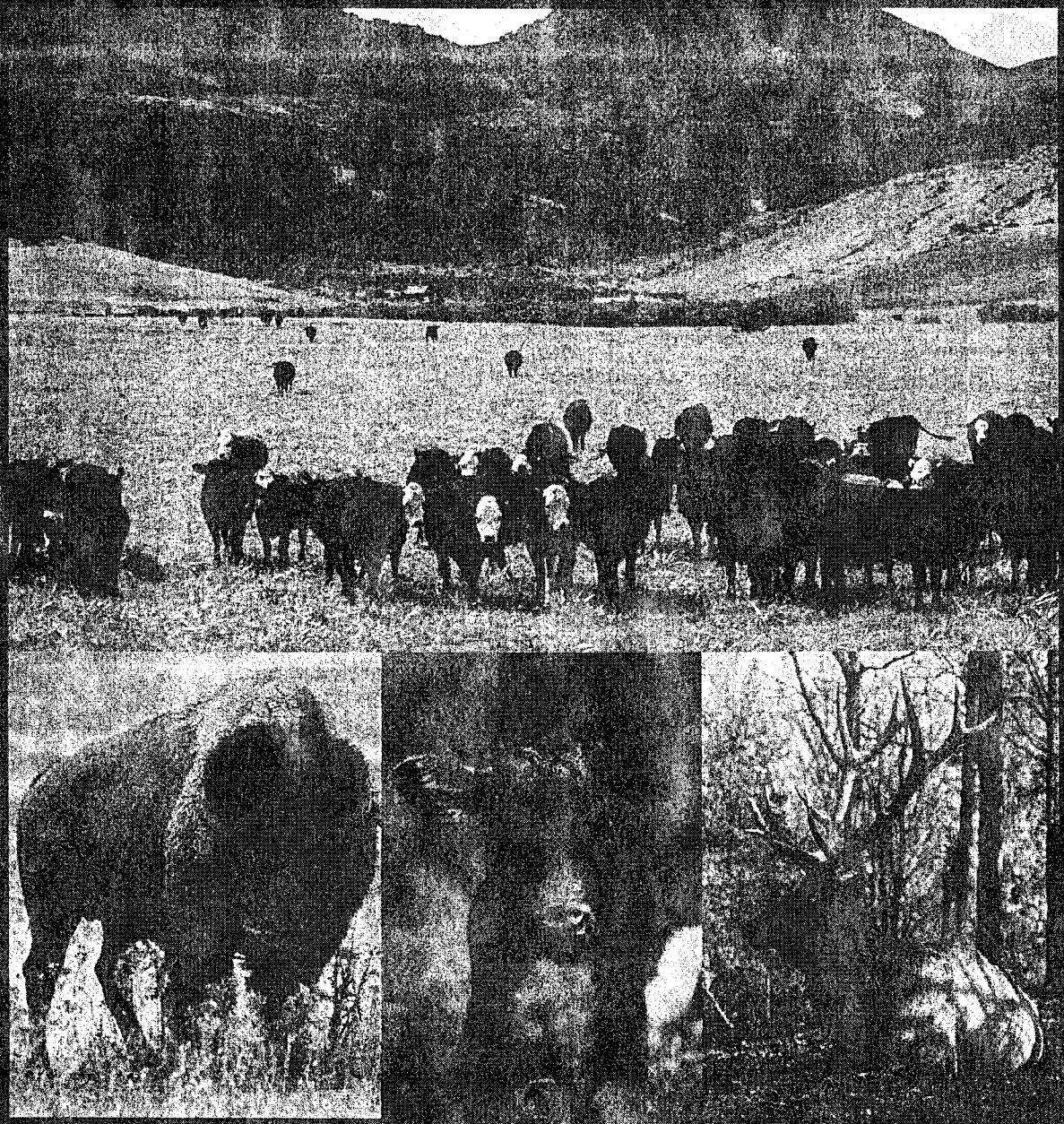
United States Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

National Brucellosis Elimination Zone Proposal



USDA APHIS VS Veterinary Services

Justification and Support

The World Organization for Animal Health (OIE) adopted the concept of regionalization to define distinct subpopulations (herds) for disease control and international trade purposes. These concepts will be applied to the NBEZ to improve upon ongoing disease control efforts.

According to the OIE, a zone or region is a clearly defined part of a country containing an animal subpopulation with distinct health status, with respect to a specific disease, for which required surveillance, control, and biosecurity measures have been applied for international trade purposes.

Historically, U.S. disease eradication programs such as tuberculosis, pseudorabies, and brucellosis have relied on a regionalized approach on a State-by-State basis. This method has been effective for disease control because eradication program standards allow States to enforce interstate movement and testing requirements.

Although regionalization at the State level has been effective, it can be costly for States when only a few livestock herds in a small geographic area are identified as affected. For brucellosis, when an affected livestock herd is identified anywhere in a State, the entire State is downgraded to the next lower level of classification in accordance with title 9, Code of Federal Regulations (9 CFR), section 78.40. When a State is downgraded, all producers in that State must meet the additional testing and mitigation requirements. The downgrade results in a costly situation for producers as well as State and Federal governments.

To minimize the impact to a whole State during an outbreak situation, 9 CFR 78.40 and the Brucellosis Eradication Uniform Methods and Rules (UM&R), October 2003, allow States to designate a two-area classification, called split-State status, in which one area has a separate brucellosis classification from the rest of the State. One benefit of split-State status is that areas considered free of brucellosis may ship livestock interstate and internationally with minimal restrictions. However, the application process for split-State status can take over a year to complete. States are responsible for the majority of the workload and are required to have the legal and financial resources necessary to implement the zone. In addition, split-State status currently requires a regulatory change each time; therefore, increasing or decreasing the size of the zone as risks change can be difficult and burdensome for the State.

As an alternative to split-State status, APHIS-VS is proposing to define a high-risk zone for livestock, the NBEZ, to reduce the impact of brucellosis in the affected GYA States. This proposal would offer several advantages. Similar to split-State status, creation of the NBEZ would allow the remainder of the State to maintain its brucellosis free status. However, the NBEZ would allow flexibility in modifying the boundaries of the zone as the risks associated with *B. abortus* change. In contrast, split-State status would require a new application to redefine the classification areas, delaying the designation. Management of the NBEZ would be a collaborative State-Federal effort, reducing the burden on each individual State and creating a more effective way to work toward brucellosis elimination in these livestock populations. The key to the plan's success is participation from all three impacted States. The efforts of the States and other organizations with a vested interest in the status of brucellosis in the domestic livestock and wildlife of the GYA will be integrated during the development of the NBEZ.

This zone would encompass an area around the GYA where potential exposure to *B. abortus* could occur. The official NBEZ boundaries will be established based on a risk assessment that considers current brucellosis surveillance and control practices in both livestock and wildlife in the GYA, the risk factors associated with transmission of brucellosis, and other ecological factors. Successfully eliminating brucellosis will require enhanced sur-

veillance and mitigations to ensure early detection of affected herds and to prevent spread of *B. abortus* outside of the NBEZ.

Implementation of this concept would allow the remainder of each State outside the NBEZ to maintain Class Free status regardless of detection of disease in livestock within the NBEZ. For the rest of the United States, creating a zone around the GYA for brucellosis management in livestock would ensure that international trade of U.S. cattle continues uninterrupted in compliance with OIE standards.

Photo courtesy Yellowstone National Park

Proposed Action Plan

Risk Assessment

As one of the first steps to establish the NBEZ, APHIS-VS will conduct a risk assessment to ensure the evaluation of all factors that may increase the risk of *B. abortus* transmission to livestock within and outside the NBEZ. Using the OIE concept of regionalization, the assessment will utilize current knowledge of brucellosis epidemiology and ecology in the GYA to establish the boundaries. Simultaneously, a herd-risk scoring tool will be developed to allow for the tiering of risk among herds within the NBEZ.

Identification of the NBEZ: To create the NBEZ, an area where herds are at greater risk of *B. abortus* exposure than surrounding populations will be identified. Epidemiological, ecological, and geographic factors will be used to define a zone with distinct and identifiable boundaries that contain a majority of the potential risk factors for *B. abortus* exposure.

Procedures to establish the NBEZ will include identification and assessment of all pathways of potential spread of *B. abortus*. This task will incorporate current scientific knowledge of the ecology, epidemiology, and disease dynamics of *B. abortus* in domestic livestock and free-ranging bison and elk. Information from investigations of brucellosis outbreaks in livestock, as well as surveillance in domestic livestock and wild populations of bison and elk, will also help identify potential risk pathways. To define the NBEZ boundaries, this information will be combined with data describing the distribution and ecology of bison and elk populations in the GYA, including migratory behavior and routes, overwintering areas, calving areas, and use of areas occupied by livestock. In addition, data on management of wild bison and elk such as feed ground use and location and hazing of bison will be considered. This information will be used to determine areas of greatest likelihood for contact between livestock and free-ranging bison and elk, and potential livestock exposure to *B. abortus*.

Disease risk is not static and can change significantly over time as production practices change, exposure mitigations are implemented, and disease management of free-ranging bison and elk populations improves. Because the system is dynamic, the NBEZ boundaries may be redefined as new data become available. This will continually ensure that the risk of exposure is adequately contained while the impact to livestock in the adjacent free zone is reduced, and surveillance and mitigation requirements are not unnecessarily imposed on herds no longer considered at significant risk.

Risk-based approach to herd management within the NBEZ: States and other entities and organizations have developed multiple herd-level risk classification tools, such as herd plans and risk factor scoring. However, these tools and their implementation vary by State. APHIS-VS and States will de-

velop a herd classification system that integrates existing tools with the goal of standardizing efforts in all three States.

A risk scoring system will be used to assess herd risk based on producer-identified risks (e.g., elk presence on property), management practices, and biosecurity. Risk levels may be further defined based on other factors, such as proximity to elk feeding grounds, elk and bison population levels, and seroprevalence rates of *B. abortus*. The risk tool will provide a standardized method for producers and animal health officials to define a herd's risk of acquiring brucellosis, identify needed mitigation to reduce risk, conduct surveillance to assure early detection, and allow movement with confidence of a herd's freedom from brucellosis. Livestock producers may have the opportunity to improve their herds' risk score by adopting mitigation strategies associated with the identified risk factors. Producers within the NBEZ will use their herd risk scores to choose which herds they add to or allow to mingle with their herds, under guidelines similar to existing herd certification programs. However, a herd's risk status will be raised if producers add from or mix with herds of a higher risk status.

Mitigations

Surveillance

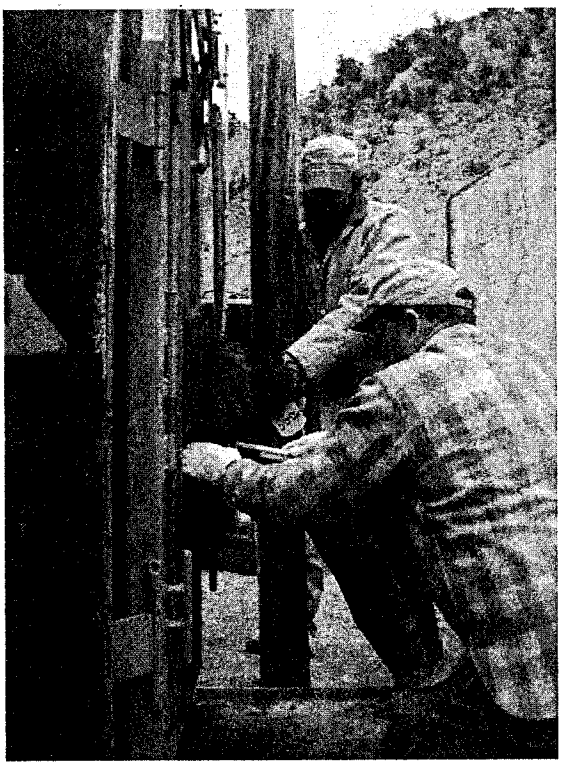
Surveillance procedures for brucellosis currently depend on the State's class status. Generally, when a State's classification is lowered, surveillance is increased, which raises costs to the producer and the State. By developing a tiered surveillance scheme that addresses surveillance outside and within the NBEZ, States will be able to utilize their resources more for brucellosis detection and elimination by focusing efforts on their portions of the NBEZ.

Although this plan focuses on addressing domestic livestock, it is important to note that effective wildlife surveillance and control implemented concurrently within the NBEZ will provide higher confidence of disease detection in livestock.

Surveillance outside the NBEZ: Depending on the findings of the risk assessment, surveillance in areas of Idaho, Montana, and Wyoming outside the NBEZ may need enhancement to ensure rapid detection of disease due to intrastate movement of animals from inside the NBEZ. Meeting these requirements will allow Idaho, Montana, and Wyoming to maintain Class Free status outside the NBEZ.

States outside the GYA will continue surveillance under the established national protocols for maintaining Class Free status per the Brucellosis Eradication UM&R. In those areas, surveillance streams used to evaluate brucellosis status will continue to include bovine brucellosis slaughter surveillance, milk surveillance using the brucellosis ring test in dairy herds, first-point testing (market surveillance), and abortion screening.

Livestock moved from within the NBEZ to slaughter or feedlots outside of the NBEZ or outside Idaho,



Montana, and Wyoming may need to be specifically targeted for surveillance testing, preferably using electronic animal movement information and mandatory identification.

Surveillance in the NBEZ: Within the defined NBEZ, brucellosis surveillance will be increased to ensure rapid detection of affected herds and prevent movement of *B. abortus* out of the zone. An appropriate level of surveillance will be recommended for all herds located inside the NBEZ.

The risk scoring system described above will be utilized to establish herd-specific surveillance protocols. Testing requirements for the lower-risk herds will be set to equal the minimum level for the NBEZ. Higher-risk herds will be subject to greater surveillance requirements. Herd-level surveillance will include movement testing, investigations of abortion events, and serologic testing of herds. Again, the amount and frequency of herd testing required will depend on the herd-risk status.

Additional mitigations: In order to prevent the spread of brucellosis within and outside of the NBEZ, several mitigation practices may be adopted. Electronic movement certificates and animal identification should be used for animals leaving the NBEZ to ensure compliance with appropriate testing requirements. This will also ensure that effective trace investigations associated with affected livestock can be performed. Additional mitigations, such as vaccination and restricting movement of livestock only to slaughter, may also be applied.

Implementation

Regulatory changes: Official establishment of the NBEZ will require regulatory changes at the Federal level. The necessary rulemaking to establish the zone according to internationally accepted guidelines will require many months to complete. The rule, however, will allow for more flexibility in modifying the zone boundaries as conditions change.

Prior to publishing the official rule that will develop the zone, APHIS-VS intends to work in close partnership with the GYA States to establish the zone boundaries and concomitant standardized surveillance activities, mitigations, and movement controls. Rapid implementation of consistent, focused disease elimination and control strategies in the zone is in the best interest of Federal and State animal health officials and producers. Initial implementation of many of these strategies does not require regulation but only the cooperative efforts of State, Federal, and producer entities. Regulatory changes at the State level will also be required, with particular attention needed on requirements for movement of livestock outside of the zone. APHIS will begin work immediately to establish zone boundaries following stakeholder and partner acceptance of the NBEZ concept.

Oversight and monitoring: State animal health officials and producer groups have worked extensively to create herd risk assessment tools, herd plans, surveillance techniques, and suggested regulatory changes. APHIS-VS will work closely with these groups to assist with standardizing these tools, leveraging them for appropriate application across the entire NBEZ. A "toolbox" of surveillance approaches, disease mitigation strategies, risk assessment approaches, and herd plans will be developed and made available to all partners and stakeholders. State and Federal animal health officials will share the use of these tools. For example, the location of a Federal or State veterinary medical officer will determine who will conduct a herd risk assessment and develop a herd plan. Oversight and monitoring of herd plans will be the State animal health official's responsibility, as it is currently. This approach will continue the long-standing cooperative effort between State and Federal officials in the brucellosis program.

Mitigation implementation and enforcement: Implementing appropriate levels of surveillance within the zone will be critical to demonstrate mitigation and movement control effectiveness. As with any sur-

veillance effort, the collection, validation, and reporting of accurate surveillance data facilitates the demonstration of effectiveness and allows for rapid response to detections of disease. Existing data collection and management systems, including the Mobile Information Management System (MIMS) brucellosis application, the Animal Health Surveillance and Monitoring System (AHSM), and components of the National Animal Identification System (NAIS), will be used to enhance surveillance capabilities in the NBEZ. Individual State and Federal animal health officials will be responsible for meeting the established surveillance standards, including reporting deadlines and criteria within their States.

Livestock movement controls will be implemented to assure the States that the risk of disease spread outside the zone is minimal. As mentioned previously, individual State authorities will be responsible for enforcing movement controls, such as ensuring that only low-risk cattle are moving, without brucellosis testing, outside the zone or that high-risk cattle are moving only to slaughter or feeding operations where the risk of spread is controllable.

A key component to effective movement control will be the zone-wide implementation of premises and animal identification. This will be combined with other efforts such as check stations, permitting, electronic movement certificates, market surveillance, slaughter surveillance, and frequent record review to provide necessary confidence in the risk mitigations employed. APHIS-VS, primarily at the VS Area Office level, will work closely with State animal health officials to continuously monitor movement information and provide rapid service to producers needing to transport livestock outside the NBEZ.

Wildlife: The NBEZ concept presented here is only part of a successful approach to brucellosis elimination in the GYA. Implementation of the NBEZ requires a concurrent planning effort with the many wildlife agencies and entities in the GYA. Consideration of the GYA as an entire ecosystem should

drive this planning process with development of potential strategies to eliminate brucellosis from bison and elk in the GYA. Numerous points exist for integration of these efforts. The Interagency Bison Management Plan has outlined strategies requiring concerted efforts for adequate spatial-temporal separation of bison and livestock. A coordinated approach to surveillance in both domestic livestock and wildlife (e.g., serologic testing and observation of abortions or orchitis) is also critical to ensuring control and elimination of brucellosis in the GYA. APHIS-VS is eager to partner with wildlife agencies and entities in the wildlife brucellosis planning effort.

Resources

An accurate estimate of the resources needed to establish and then maintain the NBEZ will not be possible until boundaries are determined, surveillance levels established, and mitigation strategies developed. Additional financial resources in the GYA States will be necessary. These funds will support additional field and technical personnel, vehicles, laboratory activities, travel, supplies, administrative and analytical support, producer incentives, and vaccination, among other needs.

APHIS-VS is currently developing an updated national brucellosis surveillance plan. The plan will incorporate strategies that include, but are not limited to, laboratory consolidation, standardizing test protocols, redirecting surveillance funds, and communication to stakeholders regarding poten-

tial changes to current brucellosis surveillance components. APHIS-VS intends to redirect resources gained from the restructured national surveillance system to the NBEZ, the area of highest brucellosis risk.

In fiscal year 2008, APHIS-VS allocated approximately $2.5 million to brucellosis work in the GYA States. These funds were used for cooperative agreements with the GYA States and universities, and for APHIS-VS personnel and activities in VS Area and Regional Offices. Total contributions from States and producers are unknown but substantial. APHIS-VS, States, and producers will continue to jointly provide the financial and personnel resources needed to create and maintain the zone.

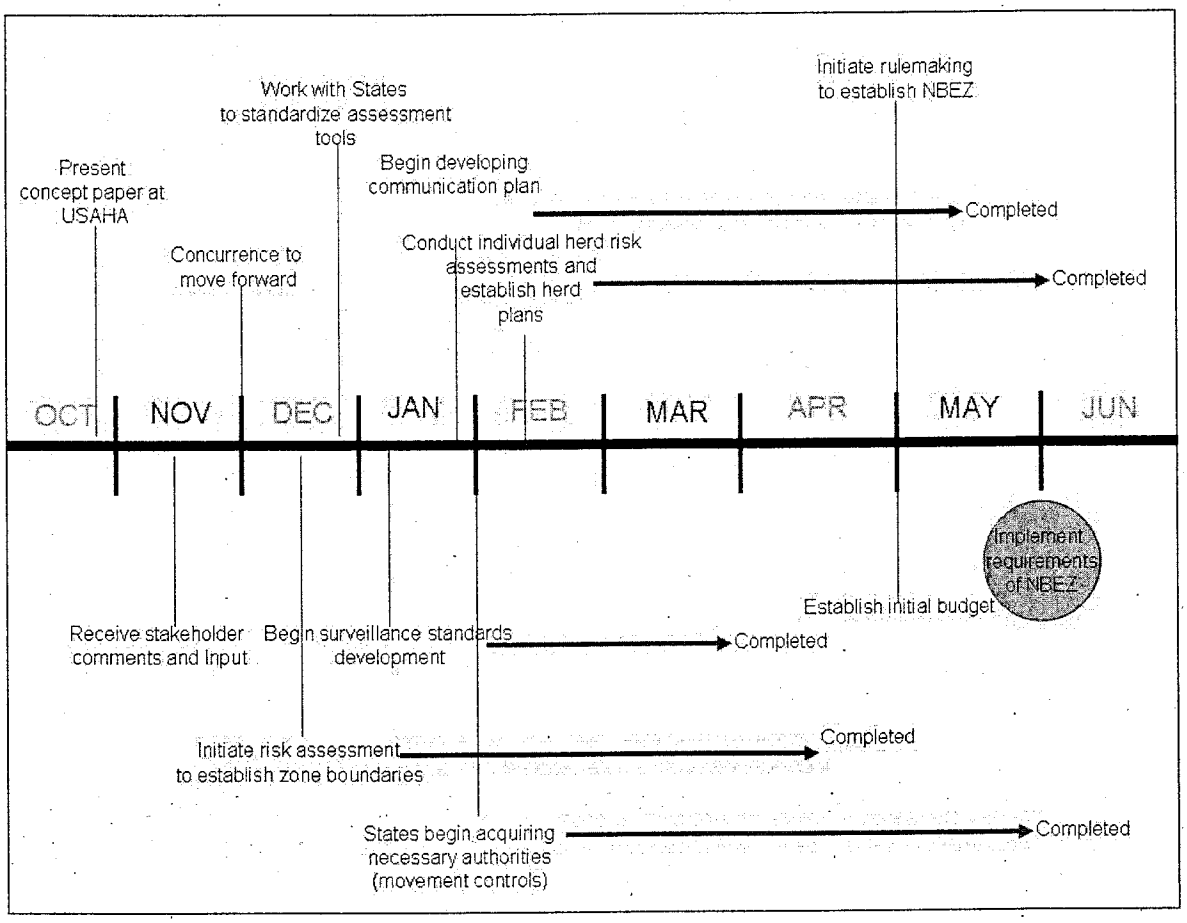
Conclusion

Elimination of *B. abortus* from the United States is nearly complete, with only a nidus remaining in wildlife reservoirs in the GYA. This problem has affected the brucellosis status of the States surrounding the GYA, adding costs and burdens to all producers.

Designation of the NBEZ would allow the remainder of the United States, including the areas outside the NBEZ in Idaho, Montana, and Wyoming, to maintain Class Free status even if an affected herd is found in the zone, thus minimizing trade and movement restrictions. In addition, creating the NBEZ would allow greater flexibility than Split-state status in redefining zone boundaries as the natural history of brucellosis evolves in the GYA.

A cooperative State-Federal effort to establish the NBEZ and efficiently utilize resources in affected States would allow the United States to eliminate brucellosis in both livestock and wildlife. To succeed, this effort will require the continued partnership of APHIS-VS with States, agencies, and industry, as well integrated planning and implementation efforts with wildlife agencies and interest groups.

Timeline


Initiate rulemaking to establish NBEZ
Work with States to standardize assessment tools
Present concept paper at USAHA
Begin developing communication plan
Completed
Concurrence to move forward
Conduct individual herd risk assessments and establish herd plans
Completed
OCT
NOV
DEC
JAN
FEB
MAR
APR
MAY
JUN
Implement requirements of NBEZ
Establish initial budget
Receive stakeholder comments and Input
Begin surveillance standards development
Completed
Initiate risk assessment to establish zone boundaries
Completed
States begin acquiring necessary authorities (movement controls)
Completed